K013428

APR 0 4 2002

510(k) Summary
MAYFIELD®/ACCISS™ Operating Arm System and MAYFIELD®/Optical ACCISS™ System
Revised Indication

Contact: Kenneth B. Miller
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Trade Names: **MAYFIELD®/ACCISS™ Operating Arm System and MAYFIELD®/Optical ACCISS™ System**

Common Name: Computer-based Image-guided Stereotactic Planning System

Classification Name: Instrument, Stereotaxic (84HAW)

Substantial Equivalence is claimed to:
K981686 StealthStation® System,
K003699 Medivision IGS System
K001153 StealthStation® Generation 3 System
K005389 VectorVision^2

K013428

Device Description: The devices are not changed either in hardware or software. They remain as shown in K955397, K982244, K991267, and K992843.

This notification only relates to a revision of the Indications for Use to a closer alignment with the Indications for Use provided for the devices shown above to which Substantial Equivalence is claimed.

All of these devices use CT or MRI data gathered prior to, or during, a surgery that is then correlated to the patient by way of various locating methods (mechanical, optical or electromagnetic) and software. This then allows the user to plan, and/or complete, the intended procedure.

Indication for Use: The MAYFIELD®/ACCISS™ Operating Arm System and the MAYFIELD®/Optical ACCISS™ System are indicated for open or percutaneous procedures for any medical condition where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, or previously placed fiducial markers, can be identified relative to a CT or MRI and the use of stereotaxic surgery may be considered appropriate. Representative uses would be for cranial, spinal and ENT procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ohio Medical Instrument Company, Inc.
Mr. Kenneth B. Miller
Manager, Regulatory
4900 Charlemar Drive
Cincinatti, Ohio 45227

APR 0 4 2002

Re: K013428
Trade Name: Mayfield®/Acciss™ Operating Arm System and Mayfield®/Optical Acciss™ System
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 28, 2002
Received: January 31, 2002

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, (Misbranding by reference to premarket notification((21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013428

Device Name: MAYFIELD®/ACCISS™ Operating Arm System and MAYFIELD®/Optical ACCISS™ System

Indications For Use:

The MAYFIELD®/ACCISS™ Operating Arm System and the MAYFIELD®/Optical ACCISS™ System are indicated for open and percutaneous procedures for any medical condition where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, or previously placed fiducial markers, can be identified relative to a CT or MRI and the use of stereotactic surgery may be considered appropriate. Representative uses would be for cranial, spinal and ENT procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format - 1 - 2 - 96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013428